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510(k) Summary K053112 1/3

1. General Information

Trade Name of Device:	"BioSign™"
Common/Usual Name:	Accessory to multi-parameter patient monitor (bedside or ambulatory)
Classification Name:	Monitor, physiological, patient
Submitters Name and Address:	Oxford BioSignals Ltd Magdalen Centre Oxford Science Park Oxford OX4 4GA United Kingdom Tel +44 (0) 1865 336170 Fax +44 (0) 1865 336180
Manufacturer:	Oxford BioSignals Ltd Magdalen Centre Oxford Science Park Oxford OX4 4GA United Kingdom

2. Device Description

BioSign™ is a software accessory to standard multiple parameter physiological patient monitors (bedside or ambulatory) or clinical information systems. It operates on a standard medical grade computer.

BioSign™ is a software device embedded in a standard medical grade computer that through advanced signal processing can combine physiological signals in order to produce a single graph representation of patient condition.

BioSign™ is a computerized analysis system that can accept multiple channels of physiological data (for example heart rate, respiratory rate, temperature, blood pressure and oxygen saturation as inputs). Through advanced signal processing, BioSign can identify changes in patient status.

3. Indications for Use

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BioSign™ is an accessory to a multi-parameter patient monitor (bedside or ambulatory) or clinical information system and is indicated for use by health care professionals with those non-pediatric high dependency care patients for whom multi-parameter patient monitoring has been routine.

BioSign™ provides the clinician with a trend graph of the patient status index based on a weighted average of five vital signs namely heart rate, respiration rate, temperature, oxygen saturation and blood pressure. The patient status index is a single measure of the patient's condition and represents how different the patient's vital signs are with respect to normality. BioSign™ is an adjunct to and is not intended to replace vital signs monitoring.

4. Substantial Equivalence

The BioSign™ device is substantially equivalent to the following devices:

Propaq 200 Series Monitors (K012451) multi-parameter physiological patient monitors. BioSign™ is a software accessory to multi-parameter physiological patient monitors and as such is substantially equivalent to the Propaq 200.

BioSign™ is an adjunct to a patient monitor and displays real time monitoring of heart rate, respiration rate, blood pressure, temperature and oxygen saturation and, therefore, the BioSign™ display is substantially equivalent to the Propaq 200 series display, which provides real time monitoring of each physiological channel.

BioSign™ additionally provides a real time trend display of the data fusion of these vital signs.

Sonicaid System 8002 (K992607) is a software accessory for the computerized analysis of antepartum cardiotocograms (CTGs). It informs the clinician whether a CTG meets a number of criteria that are indicative of a normal CTG .These criteria were established by examination of historical clinical data.

BioSign™ is substantially equivalent to Sonicaid System 8002 in that its displayed graphical representation of the fused vital signs is created by computer analysis and provides decision support to a clinician in the determination of normality based on a model derived from historic clinical data.

A-2000 EEG Monitor with BIS (K030267) is an EEG monitoring system that monitors the state of the brain of an anesthetized or sedated patient. Raw EEG information obtained from patient sensors is processed with the complex Bispectral Index (BIS) algorithm and a number between 1 and 100 calculated and displayed to the clinician. This BIS index and associated trend graph provides a direct indication of the patient's level of anesthesia.

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BioSign™ is substantially equivalent to the A-2000 EEG Monitor with BIS in that it also takes a patient's physiological signals and processes them in order to provide the clinician with an index and associated trend graph indicative of the patient's state.

5. Performance Studies

Design verification: Design verification testing of the BioSign™ hardware and software against the specified requirements has been conducted and the BioSign™ device has been found to meet the specifications.

Design validation: Design validation testing of the BioSign™ patient status index model has been conducted and concluded that device specifications conformed with user needs and intended use.

Electrical Safety: BioSign™ systems comply with BS EN 60601-1-1:2001, "Safety requirements for medical electrical systems."

6. Conclusion

Based upon the indications for use and performance studies BioSign™ has been shown to be substantially equivalent for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 3 1 2006

Oxford BioSignals Limited
c/o Mr. Howard M. Holstein
Regulatory Counsel
Hogan & Hartson, LLP
555 13th St NW
Washington DC 20004

Re: K053112
Trade/Device Name: BioSign™
Regulation Number: 21 CFR 870.2300
Regulation Name: Physiological Patient Monitor (without arrhythmia detection or alarms)
Regulatory Class: Class II
Product Code: MWI
Dated: November 4, 2005
Received: November 4, 2005

Dear Mr. Holstein:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

B Zuckerman for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 4 INDICATIONS FOR USE

510(k) Number (if known): K053112

Device Name: **BioSign™**

Indications For Use:

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BioSign™ provides the clinician with a trend graph of the patient status index based on a weighted average of five vital signs namely heart rate, respiration rate, temperature, oxygen saturation and blood pressure. The patient status index™ is a single measure of the patient's condition and represents how different the patient's vital signs are with respect to normality. BioSign™ is an adjunct to and is not intended to replace vital signs monitoring

Warning: Federal (USA) law restricts this device to sale by or on the order of a physician

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

B Yamamura

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K053112